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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,570	02/06/2002	Vitaly Vodyanoy	35721/243744 (5721-18)	6923
826	7590	12/29/2004	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			CHEU, CHANGHWA J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,570	Applicant(s) VODYANOV ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and affidavit filed on 11/5/2004 have been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2, 20-22 are cancelled.
2. Currently, claims 1, 3-19, 23-25 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated over Wagner et al. (US 6630358)

Wagner et al. teach a protein array for in vitro screening of biomolecular activity. Wagner et al. teach immobilizing a plurality of peptides of interest on the organic thinfilm, such as Langmuir-Blodgett film, of a sensor substrate (Col. 7, line 18-28; Abstract). Wagner et al. also disclose various means for detection, including fluorescence correlation spectroscopy (FCS), infrared range, optical waveguides, fluorescence resonance energy transfer (FRET) (Col. 26, 17-25). The detection methods can be used to both quantitative and qualitative determination of the interest of peptides and inherently include measurement of the signals due to the exposing of the peptides to the sensor (Col. 26, line 17-20).

With respect to claim 8-9, Wagner et al. teach using biotin-streptavidin system to increase specificity and selectivity for the target molecules in the protein array assay (Col. 24, line 17-25).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Ebato et al. (Anal. Chem. 1994 Vol. 66: 1683).

Wagner et al. reference has been discussed but is silent in using of spacer for coupling the peptides of interest.

Ebato et al. disclose that using a spacer in the Langmuir-Blodgett film can increase coupling of the target molecules (See Abstract; Figure 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al. with the spacer technique as taught by Ebato et al. in order to increase the sensitivity of the assay.

5. Claims 10-13, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Samoylova et al. (Muscle & Nerve 1999 April, page 460).

Wagner et al. reference has been discussed but does not explicitly teach *in vivo* screening of potential ligands.

Samoylova et al. disclose a muscle-specific peptide of interest, i.e. ASSLNIA, can enhance *in vivo* skeletal and cardiac muscle binding (See Abstract and Method). Samoylova et al. teach using phage library encoding the peptides of interest for *in vivo* screening candidate ligands in mice model (See Figure 3 and Abstract). The phage selected process includes several rounds of passing phage expressing peptides (See page 462, third paragraph in Results, and Figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have motivated Wagner et al. to incorporate the muscle-specific ASSLNIA peptide (peptide of interest)

to the sensor surface to screen candidate muscle-specific binding ligands with reasonable expectation of success because it has been shown that ASSLNIA peptide is a muscle-specific peptides and it can enhance binding of ligands to the muscle tissues.

6. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Hengerer et al. (Biosensor & Bioelectronics 1999 14: 139).

Wagner et al. reference has been discussed but is silent in using piezoelectric crystal or acoustic wave sensor as the detection means.

Hengerer et al. disclose an immunosensing system based on a quartz crystal microbalance (QCM), such as acoustic sensors on piezoelectric crystals vibration to detect target molecules in a sample (See Abstract). Hengerer et al. teach coupling (e.g. immobilized) the peptides of interest on the surface of the sensor and quantifying the signals output from the sensors for detecting corresponding ligands (page 140, second paragraph; Figures 1-6). Therefore, it would have been obvious to one ordinary skilled in the art at the time the invention was made to have provided Wagner et al. the alternative means for detection such as piezoelectric crystal or acoustic wave sensor as taught by Hengerer et al. since analogous field is involved, e.g. measuring peptides immobilizing on a substrate, and alternative means of measurement merely requires routine practice in the art.

Allowable Subject Matter

7. Claim 3-5, 23-25 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.
8. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or fairly suggests preparing a Langmuir-Blogett film for immobilizing peptide of interest with specific features as recited in claim 3, including comprising at least one

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phospholipid containing no more than 25% of a volatile organic solvent, immersing into an aqueous subphase at about 90-170 degrees to an air/liquid interface where the subphase comprising at least one monovalent cation and at least one bivalent cation, and delivering at a rate of about 0.02-4.0 ml per minute for form a monolayer and compressing with an optimal surface pressure.

Response to Applicant's Arguments

Declaration/Affidavit

9. Applicant's declaration filed on 11/5 has been reviewed and is persuasive in overcoming the 35 USC §102 (a) rejections as anticipated by Pathirana et al. (Biosensor & Bioelectronics 2000 Vol. 15: 135) as set forth in the previous Office Action. Accordingly, rejections of claims 1-4, 14-15, 23-24 are withdrawn.

10. Applicant's arguments with respect to claims 1, 3-19, 23-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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December 22, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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12/26/04